

Real-Time Dynamic Intraocular Pressure Fluctuations During Microcoaxial Phacoemulsification Using Different Aspiration Flow Rates and Their Impact on Early Postoperative Outcomes: A Randomized Clinical Trial

Vaishali Vasavada, MS; Shetal M. Raj, DO, MS; Mamidipudi R. Praveen, DOMS;
Abhay R. Vasavada, MS, FRCS; Bonnie A. Henderson, MD; Priyadarshi K. Asnani, DNB

ABSTRACT

PURPOSE: To compare the impact of varying fluidic parameters on intraoperative intraocular pressure (IOP) fluctuations and postoperative outcomes.

METHODS: Prospective randomized study of 80 eyes undergoing cataract surgery that were randomly assigned to low (aspiration flow rate: 20 cc/min; bottle height: 90 cm; vacuum: 400 mm Hg) and high (aspiration flow rate: 40 cc/min; bottle height: 110 cm; vacuum: 400 mm Hg) fluidic parameter groups. Real-time dynamic intraoperative IOP was measured during nuclear fragment removal. Mean maximum and minimum IOP and percentage reduction in IOP from maximum were compared between groups. Postoperatively, the rate of change in central corneal thickness and anterior chamber inflammation at days 1 and 7, endothelial cell density at 3 months, and corneal clarity on day 1 were compared.

RESULTS: Minimum IOP in the low and high parameters groups was 35 ± 4.0 and 34.5 ± 6.8 mm Hg, respectively. Maximum IOP in the low and high parameters groups was 69 ± 3.0 and 85 ± 1.2 mm Hg, respectively ($P < .002$). Mean percent reduction from maximum was 59% in the high parameters group compared to 41% in the low parameters group, with the difference being statistically significant ($P < .002$). Rate of change in central corneal thickness was greater in the high parameters group at postoperative days 1 and 7 ($P < .001$). Anterior chamber inflammation and corneal clarity on the first postoperative day were significantly better in the low parameters group.

CONCLUSIONS: Higher aspiration flow rate and bottle heights are associated with high intraoperative IOPs of up to 85 mm Hg. Prolonged elevated IOP during cataract surgery was found to have more anterior segment inflammation and more edematous corneas.

[J Refract Surg. 2014;30(8):534-540.]

It has been recognized that cataract surgery causes substantial fluctuations in intraocular pressure (IOP) during hydrodissection, nuclear fragmentation, irrigation and aspiration, and intraocular lens (IOL) insertion.¹⁻⁶ Clinical studies have recognized that high fluidic parameters raise intraoperative IOP values beyond the normal range, which can compromise blood flow to the optic nerve and retina in vulnerable eyes.⁷⁻¹¹ In the context of phacoemulsification, objective monitoring of IOP has led to recommendations to modify surgical techniques and to develop improved machine fluidics.

In a previous randomized clinical study,¹² we reported that the use of higher bottle height and aspiration flow rate (AFR) resulted in more Descemet's folds, anterior segment inflammation, and thicker corneas in the early postoperative period. Using a higher AFR and bottle height makes the surgical procedure faster and also reduces the amount of ultrasound energy used, whereas a lower AFR and bottle height reduce the speed of the procedure. However, lower fluidic parameters are safer because they reduce the trauma caused by fluid turbulence and damage to the surrounding tissues can be minimized. Although experimental trials have been conducted on the dynamics between varying fluidic parameters and IOP fluctuations during microcoaxial phacoemulsification,¹ there is a relative paucity of literature on these dynamics in a real-time clinical setting. In the current study, we measured the dynamic real-time IOP fluctuations using different AFRs and bottle heights during microcoaxial phacoemulsification. We also correlated our findings with postoperative outcomes.

From Iladevi Cataract & IOL Research Center, Ahmedabad, India (VV, SMR, MRP, ARV, PKA); and Ophthalmic Consultants of Boston, Tufts University School of Medicine, Boston, Massachusetts (BAH).

Submitted: August 20, 2013; Accepted: April 10, 2014; Posted online: August 5, 2014

The authors have no financial or proprietary interest in the materials presented herein.

Correspondence: Abhay R. Vasavada, MS, FRCS, Iladevi Cataract & IOL Research Center, Gurukul Road, Memnagar, Ahmedabad - 380 052, India. E-mail: icirc@abhayvasavada.com

doi:10.3928/1081597X-20140711-06

TABLE 1
Surgical Parameters for Phacoemulsification: Low and High Parameters

Group	U/S-Preset Amplitude (%)	Pulses per Second	% On Time	Vacuum (mm Hg)	AFR (cc/min)	Bottle Height (cm)
Low parameters						
Sculpting	60	40	40	80	20	70
Chopping	60	40	40	Up to 400 ^a	20	70
Fragment removal	60	40	40	300 (reduced progressively)	20	90
High parameters						
Sculpting	60	40	40	80	40	90
Chopping	60	40	40	Up to 400 ^a	40	90
Fragment removal	60	40	40	300 (reduced progressively)	40	110

U/S = ultrasound; AFR = aspiration flow rate

^aVacuum level decided based on the grade of nuclear sclerosis.

PATIENTS AND METHODS

This prospective randomized clinical trial included 80 eyes (80 patients) with age-related cataract undergoing microcoaxial phacoemulsification at the Iladevi Cataract & IOL Research Center from March to October 2011. Patients with nuclear sclerosis grades 2 and 3 (as per the Lens Opacities Classification System III classification) were included. Exclusion criteria were: presence of glaucoma, shallow anterior chamber (anterior chamber depth < 2.1 mm), pupillary dilatation less than 6 mm, extremely soft or dense cataracts (grades 1 and > 4, according to the Lens Opacities Classification System III classification), posterior polar cataract, subluxated cataract, white mature cataract, diabetic retinopathy, high myopia (defined as axial length > 25 mm), uveitis, or previous ocular trauma. Only 1 eye of each patient was randomly included in the study. The Institutional Review Board approved the study and informed consent was obtained from all patients. The study followed the tenets of the Declaration of Helsinki.

Central corneal thickness (CCT) was assessed by ultrasonic pachymetry (Ocuscan; Alcon Laboratories, Inc., Fort Worth, TX) preoperatively and postoperatively. A noncontact specular examination was performed using the Topcon SP-2000P (Topcon, Itabashi, Tokyo) to study the corneal endothelium. Randomization was performed using a computer-generated random number table. Immediately prior to commencement of surgery, an unscrubbed nurse in the operating room informed the surgeon of the parameters to be employed for that particular patient. Patients were randomized in one of two groups depending on the fluidic parameters used.

In the low parameters group (n = 40 eyes), emulsification was performed using the following fluidic parameters: bottle height between 70 and 90 cm, a

fixed AFR of 20 cc/min, and vacuum settings up to 400 mm Hg, depending on the grade of nuclear sclerosis. In the high parameters group (n = 40 eyes), emulsification was performed using the following fluidic parameters: bottle height between 90 and 110 cm, a fixed AFR of 40 cc/min, and vacuum settings up to 400 mm Hg, depending on the grade of nuclear sclerosis.

A single surgeon (ARV) performed all of the surgeries using a standardized technique¹³ and longitudinal ultrasound in pulse mode on the Infiniti Vision System (Alcon Laboratories, Inc.). No attempt was made to mask the surgeon to the surgical parameters being used. The parameters used during each stage of surgery are shown in **Table 1**.

SAMPLE SIZE CALCULATION

IOP fluctuation values were compared using high and low parameters in a pilot study during nuclear quadrant removal. The average IOP fluctuation was observed to be 20 and 30 mm Hg for low and high fluidic parameters, respectively. A difference of 10 mm Hg or less was treated as representing equivalence between the groups. A sample size of 30 patients in each group would have a power of 80% at an alpha level of 5%. Based on this, 40 eyes were recruited in each group.

THE IOP MEASUREMENT SET-UP

The IOP measurement system was first reported and validated in 2006¹⁴ and comprises four components: a pressure sensor connected to a transducer, a signal amplifier, an IOP recording device, and a display unit (**Figure A**, available in the online version of this article). A cannula (external diameter: 0.9 mm; internal diameter: 0.5 mm) was connected to flexible PVC tubing (external diameter: 1 mm; internal diameter: 0.5 mm). This was, in turn, connected to a disposable pressure

TABLE 2

Comparison of Intraoperative Outcome Measures: Low vs High Intraoperative Surgical Parameters

Parameter	Low Parameters Group	High Parameters Group	P ^a
Surgical time (min)	7.11 ± 2	5.11 ± 1.7	.001
Fluid used (mL)	110 ± 25	90 ± 20	.001
CDE	25.45 ± 12.95	15.16 ± 7	.002

CDE = cumulative dissipated energy

^aKruskal–Wallis test.

transducer (Edwards Lifesciences, Irvine, CA). This transducer converts pressure fluctuations into DC electric signals that are received by an electronic receiver. The receiver feeds the voltage to a signal amplifier that amplifies the signal 1,000 times. The amplified signals are converted in real time to digital signals using specialized firmware (PICO Scope; Pico Technology, Cambridgeshire, United Kingdom) that simultaneously displays and logs data on a computer. For display purposes, the range of pressure was 0 ± 200 mm Hg on the y-axis and the time scale was 50- μ s intervals. Finally, a separate display set-up allowed simultaneous and synchronized overlay of the IOP graph and surgery (**Figure B**, available in the online version of this article). A video mixer combined inputs from the computer to the live surgical video display from the operating microscope (including information on the surgical parameters from the Infiniti Overlay System) (**Figure C**, available in the online version of this article).

RECORDING THE IOP

IOP was recorded during the following phases of phacoemulsification: sculpting, nuclear division, and nuclear quadrant removal. Following hydrodissection, the sensor cannula was introduced in the anterior chamber through the superior paracentesis. A baseline steady-state IOP trace was obtained with the foot pedal in the 0 position, which was used to confirm the functioning of the set-up. An IOP value in the range of 10 to 20 mm Hg at baseline was considered evidence for proper functioning (based on a pilot observation of 20 eyes) because the transducer was pre-calibrated.

ANALYZING THE IOP

A single observer reviewed the recorded IOP tracings for each eye. The maximum and minimum IOPs were noted. The percentage reduction from maximum IOP was then calculated as: (maximum IOP – minimum IOP) / maximum IOP $\times$ 100. For analysis,

the maximum IOP, minimum IOP, and percent reduction in IOP from the maximum during the three phases were compared between the groups.

OUTCOME MEASURES

INTRAOPERATIVE OUTCOME MEASURES

Surgical time and fluid used were measured from the commencement of sculpting to the conclusion of epinucleus removal. Cumulative dissipated energy was recorded from the Infiniti display.

The main outcome measure was to compare real-time maximum IOP, minimum IOP, and percentage reduction in IOP during all phases, but mainly quadrant removal.

POSTOPERATIVE OUTCOME MEASURES

The rate of change in CCT was measured preoperatively to postoperative days 1, 7, and 30 and was compared between the groups. On postoperative day 1, corneal clarity was graded on the slit lamp as clear or presence of Descemet's membrane folds. Anterior segment inflammation was graded according to Hogan's criteria and IOP was measured and compared between the groups on postoperative day 1. The percentage change in endothelial cell density was compared at 3 months postoperatively. A single examiner who was masked to the parameters used evaluated all of the postoperative observations.

RESULTS

The mean age of the patients was 64.42 ± 5.43 years (range: 45 to 74 years) in the low parameters group and 62.67 ± 8.79 years (range: 41 to 77 years) in the high parameters group ($P = .52$). The mean grade of nuclear sclerosis in the low and high parameters groups was comparable (3.01 ± 0.65 and 3.11 ± 0.50 , respectively; $P = .67$). Mean axial length was 22.72 ± 2.3 mm and 23.1 ± 2.1 mm in the low and high parameters groups, respectively ($P = .7$).

The surgical time, amount of fluid used, and cumulative dissipated energy were significantly greater in the low parameters group compared to the high parameters group ($P < .002$) (**Table 2**).

Peak IOP values were achieved in both groups when the surgeon was using foot position 1 (irrigation only) and when complete occlusion of the phacoemulsification tip occurred during the chopping or quadrant removal phases. In the low parameters group, the mean baseline IOP in foot position 1 was 52.8 ± 2.6 mm Hg (range: 48 to 56 mm Hg) at a 70-cm bottle height and 68 ± 4.2 mm Hg (range: 65 to 74 mm Hg) at a 90-cm bottle height. In the high parameters group, this value was 69.2 ± 3.0 mm Hg (range: 67 to 74 mm Hg) at a 90-cm bottle height and 86 ± 3 mm Hg (range: 79 to 90 mm Hg) at a 110-cm bottle height.

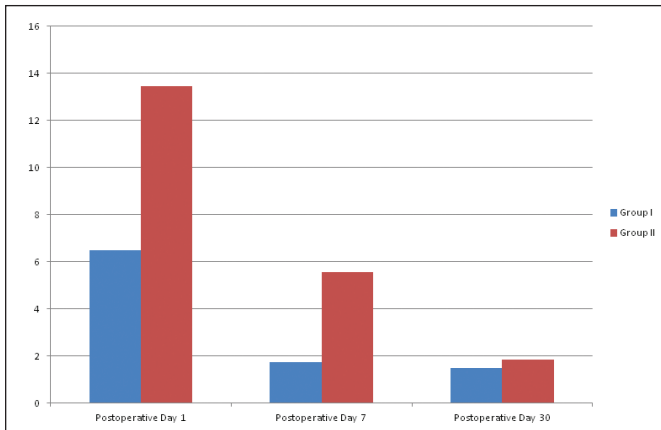


Figure 1. Comparison of the mean rate of change of central corneal thickness between the low (group 1) and high (group 2) fluidic parameters groups from preoperatively to postoperative days 1, 7, and 30.

Table A (available in the online version of this article) delineates the maximum, minimum, and mean percentage reduction in IOP from the maximum. Mean percentage reduction of IOP from the maximum during sculpting was 12% in both groups. During nuclear division, the mean percentage reduction from the maximum was 35% and 51% for the low and high parameters groups, respectively. However, the difference was not statistically significant. During quadrant removal, the maximum IOP and mean percentage reduction of IOP from the maximum were lower in the low parameters group (41%) compared to the high parameters group (59%), with the difference being statistically significant (**Table A**).

POSTOPERATIVE OUTCOMES

Mean IOP on the first postoperative day was comparable (low parameters group = 14.6 mm Hg vs high parameters group = 14.7 mm Hg, $P = .859$). Furthermore, 4 eyes had IOPs of 22 (1 eye), 23 (1 eye), and 24 (2 eyes) mm Hg in the high parameters group on the first postoperative day; they were treated with 0.5% timolol eye drops.

Preoperatively, the CCT in both groups was comparable ($P = .65$) (**Table B**, available in the online version of this article). A statistically significant difference in the rate of change in CCT was observed between the two groups on postoperative days 1 and 7 ($P < .001$). However, there was no statistically significant difference in the rate of change in CCT between the two groups at 1 month postoperatively ($P = .20$) (**Figure 1**). Three months postoperatively, there was no statistically significant percentage change in the preoperatively measured endothelial cell density (**Figure 2**).

Using the test of proportions on postoperative day 1, there was a statistically significant difference in

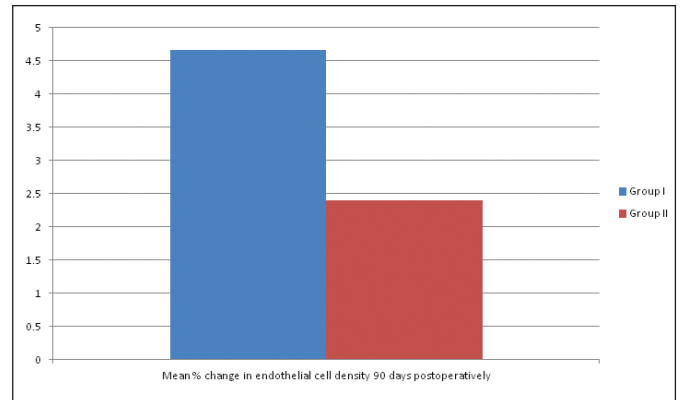


Figure 2. Comparison of the mean percentage change of endothelial cell density between the low (group 1) and high (group 2) fluidic parameters groups from preoperatively to postoperative day 30.

anterior segment cells and flare ($P = .01$), corneal clarity ($P < .001$), and corneal edema ($P < .04$) (**Table 3**). On the first postoperative day, 7 eyes in the high parameters group had Descemet's membrane folds, whereas there were none in the low parameters group ($P = .04$, using the test of proportions) (**Table 4**).

DISCUSSION

Several factors influence the IOP level inside the eye, including bottle height, preset vacuum, AFR, tubing compliance, ocular rigidity, size of the phacoemulsification tip, and tightness of the incision.¹⁵⁻¹⁹ Not only do high bottle heights raise intraoperative IOPs and compromise blood flow to the optic nerve and retina in vulnerable eyes,⁷⁻¹¹ but they can also adversely affect the health of the corneal endothelium within a short duration¹⁹ and cause exaggerated anterior chamber inflammation. Although "slow-motion phacoemulsification"²⁰ and the "step-down technique"²¹ have demonstrated the clinical benefits of using low fluidic parameters during phacoemulsification, our study is the first of its kind to provide objective evidence in a clinical setting documenting real-time dynamic IOP fluctuations with different AFRs and bottle heights and correlating it with early postoperative outcomes.

There are previous studies on IOP measurement during various intraocular surgeries on animal^{7,22} and human^{3,5-7,23} eyes. Some experiments have placed a pressure transducer in the vitreous cavity to capture IOP values during cataract surgeries. Others have obtained pressure values from along the infusion line,^{11,24,25} providing only an indirect measurement of IOP. In another study, a pneumoelectric sensor was connected to the eye through an air-filled tube, which provided indirect measurement of IOP from the eye.²⁴ All of these systems generated an isolated graph of IOP recording at a later stage that was then correlated with

TABLE 3
Comparison of Anterior Segment Inflammation on the First Postoperative Day Between the Two Groups

Grade	< 2 Cells (% of Eyes)	≥ 2 Cells (% of Eyes)
Anterior chamber cells		
Low parameters group	34	6
High parameters group	10	30
<i>P</i>	.01	.01
Anterior chamber flare		
Low parameters group	33	7
High parameters group	10	30
<i>P</i>	.01	.01

the surgical parameters. The current system allowed us to view real-time dynamic changes in IOP simultaneously with the surgical video and parameters used.

We observed that the high parameters group had a higher baseline IOP. This may be directly attributed to the higher bottle height. During the nuclear division and quadrant removal phases, the occasional occlusion of the tip resulted in a rise in IOP levels that was close to the peak level. The subsequent occlusion break was accompanied by a sharp decrease in IOP, which was more pronounced in the high parameters group compared with the low parameters group. IOP values decreased in both groups at the occlusion break, with the fluctuation being greater when higher parameters were used.

The advantage of using a high bottle height during nuclear quadrant removal is that it increases the anterior chamber depth, thereby allowing faster refilling of the chamber after the occlusion break. Furthermore, a high AFR needs to be supplemented by a higher bottle height to compensate for the greater outflow of fluid. However, the disadvantage of a high AFR and bottle height is that it causes greater IOP fluctuations and turbulence in the anterior chamber.

In the current study, a maximum IOP of 86 mm Hg was achieved when using an AFR of 40 cc/min with a bottle height of 110 cm. This finding was consistent with a recent study¹⁹ that showed that the maximum IOP was as high as 60 mm Hg when simulated phacoemulsification was performed at a bottle height of 65 cm and that increasing the bottle height led to a higher alteration of fluid flow in the anterior chamber. While evaluating the technique of one-handed phacoemulsi-

TABLE 4
Comparison of the Incidence of Corneal Clarity, Corneal Edema, and Descemet's Membrane Folds on Slit-lamp Examination on the First Postoperative Day

Group	Clear Cornea (% of Eyes)	Corneal Edema (% of Eyes)	Descemet's Membrane Folds (% of Eyes)
Low parameters group	36	4	0
High parameters group	11	12	7
<i>P</i>	.001	.04	–

fication with low fluidic parameters in porcine eyes, Corydon et al.²⁶ found that IOP remained much more stable when phacoemulsification was done with low flow rates and vacuum settings than with the higher standard settings; the authors also observed that lowering the parameters would reduce surgical trauma to the eye. Wilbrandt and Wilbrandt³ evaluated IOP fluctuations with different phacoemulsification approaches and found that a steady IOP was maintained with only minor fluctuations when using their “slow-motion” approach.

It is well documented that corneal edema, change in CCT, and corneal endothelial cell loss are indicators of surgically induced corneal trauma.²⁷⁻³⁰ In the current study, eyes in the low parameters group had significantly lower rates of change in CCT postoperatively. Eyes in the high parameters group had a greater incidence of Descemet's membrane folds and also a significant increase in anterior segment inflammation on the first postoperative day. However, these observations are transient and suggestive of corneal insult, but not definitive. Furthermore, there was no significant difference in the percentage change of endothelial cell density between the two groups at 3 months postoperatively. Intraoperatively, we noticed that using lower aspiration parameters allowed us to continue emulsifying the lens fragments at a posterior plane away from the corneal endothelium until we had removed all of the fragments without risking posterior capsule rupture or uveal tissue aspiration. As a result, the incidence of mechanical contact of the lens fragments with the corneal endothelium and the impact of fluid turbulence was lowered. We speculate that this might lead to reduced endothelial damage and a reduced breakdown of the blood–aqueous barrier. In a previous clinical study, we reported that the use of a higher bottle height resulted in more Descemet's membrane folds, anterior segment inflammation, and thicker corneas in

the early postoperative period.¹² One reason for this could be that when using a higher AFR and bottle height, absolute IOP and IOP fluctuations are higher.

A limitation of our study is that we have not measured the fluid leakage from the incisions. However, even with leakage, the IOPs were found to have a maximum of 86 mm Hg. We also did not measure the duration for which maximum IOP levels were maintained.

The results of our study objectively consolidated the perceived notion that using high fluidic parameters (ie, bottle height and AFR) can lead to higher absolute IOPs and larger IOP fluctuations during phacoemulsification. We believe that most cataract surgeons may be unaware of the magnitude of the elevated IOPs during routine phacoemulsification surgery. Understanding IOP fluctuations may be important for patients who already have compromised optic nerves and other comorbid ocular diseases. As cataract surgery is becoming “refractive cataract surgery” and as we move toward better postoperative outcomes with newer technologies (eg, femtosecond laser-assisted cataract surgery),³¹⁻³⁵ all factors that may influence intraoperative and postoperative outcomes need to be kept in mind and refined.

In a clinical scenario, our study showed that performing microcoaxial phacoemulsification with an AFR of 20 cc/min and a bottle height of 90 cm resulted in lower absolute IOPs and lesser IOP fluctuations. In turn, this resulted in clearer corneas on postoperative day 1 and decreased anterior segment inflammation.

AUTHOR CONTRIBUTIONS

Study concept and design (ARV, MRP); data collection (PKA, SMR, VV); analysis and interpretation of data (BAH, ARV, SMR, VV); drafting of the manuscript (PKA, MRP, SMR, VV); critical revision of the manuscript (BAH, ARV, SMR); statistical expertise (MRP); administrative, technical, or material support (ARV); supervision (ARV, VV)

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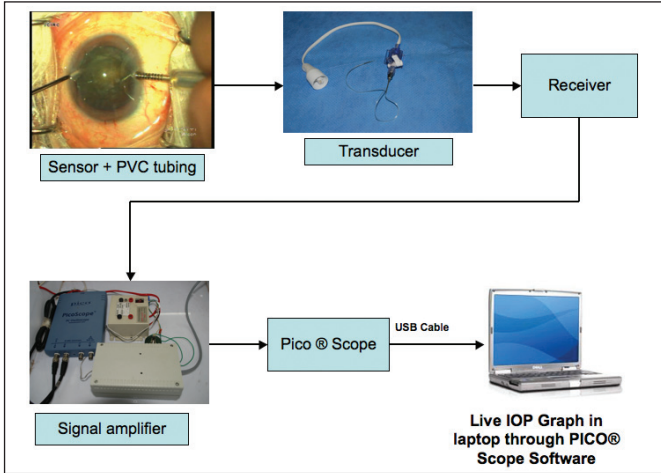


Figure A. The components of the intraocular pressure (IOP) measuring set-up. A Blumenthal cannula was inserted in the anterior chamber, which was connected to a transducer. The signals then traveled to an amplifier and finally in a computer that had the PICO Scope software (Pico Technology, XXX, XXXAQ2).

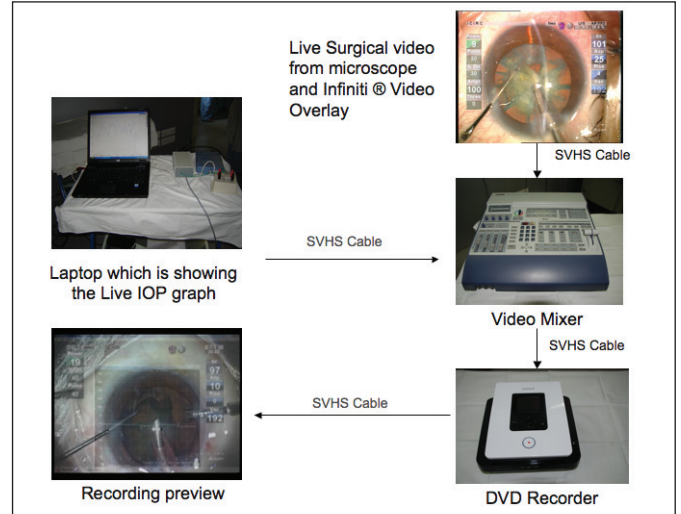


Figure B. The surgical video from the operating microscope and intraocular pressure (IOP) graph were both fed into a video mixer that provided output in which the surgical video was overlaid with the IOP recording graph.

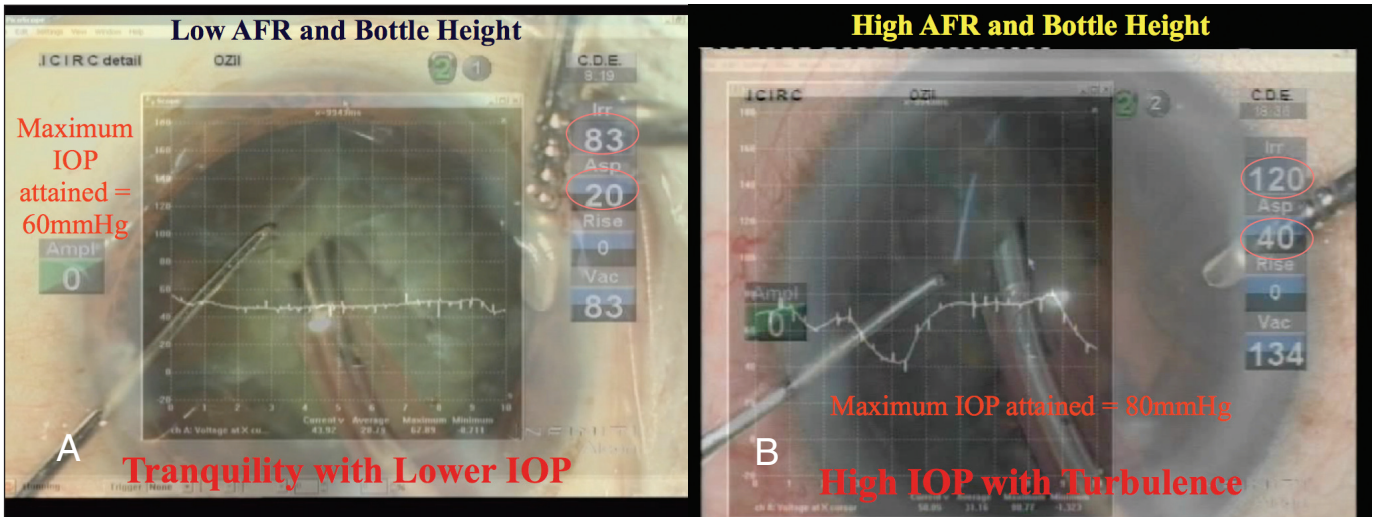


Figure C. Representative photograph of the surgical video and intraocular pressure (IOP) graph overlay. The real-time IOP changes could be well correlated with the surgical events. (A) Low parameters showed lower absolute IOP with lesser fluctuations, as seen by a smooth trace. (B) High parameters showed higher absolute IOP with greater fluctuations, as seen by a bumpy trace.

TABLE A
Comparison of the Absolute IOP and IOP Fluctuations During Different Stages of Phacoemulsification Between Low and High Parameters

IOP	Low Parameters Group	High Parameters Group	P ^a
Sculpting			
Maximum (mean ± SD)	52.5 ± 1.5	69.0 ± 1.0	–
Minimum (mean ± SD)	50.9 ± 1.5	64.5 ± 0.9	–
Mean % reduction in IOP from maximum ^b	12	12	NS
Division			
Maximum (mean ± SD)	54.0 ± 1.3	69.0 ± 0.9	–
Minimum (mean ± SD)	35.0 ± 2.0	34.0 ± 1.4	–
Mean % reduction in IOP from maximum ^b	35	51	NS
Quadrant removal			
Maximum (mean ± SD)	69.0 ± 3.0	85.0 ± 1.2	–
Minimum (mean ± SD)	35.0 ± 4.0	34.5 ± 6.8	–
Mean % reduction in IOP from maximum ^a	41	59	.002

SD = standard deviation; IOP = intraocular pressure; NS = not significant

^aIndependent t test; P < .05 considered statistically significant.

^bPercentage reduction in IOP from maximum = [(maximum IOP – minimum IOP) / maximum IOP] × 100.

TABLE B
Comparison of Preoperative and Postoperative Central Corneal Thickness (μm) Between Low and High Parameters

CCT	Low Parameters Group		High Parameters Group	
	Preoperative	Postoperative	Preoperative	Postoperative
Day -1	550.52 ± 35.34	585.84 ± 33.61	545.48 ± 41.73	617.92 ± 40.09
Day -7	550.52 ± 35.34	559.92 ± 33.29	545.48 ± 41.73	575.52 ± 46.27
Day -30	550.52 ± 35.34	558.60 ± 34.23	545.48 ± 41.73	555.60 ± 42.25

CCT = central corneal thickness